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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,503 9d004,946	08/28/1998	ROBERT D. AINSWORTH	11770	3597
25213	7590	08/23/2005		
HELLER EHRMAN LLP 275 MIDDLEFIELD ROAD MENLO PARK, CA 94025-3506				
EXAMINER KENNEDY, SHARON E				
ART UNIT		PAPER NUMBER		
3762				

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/143,503 ~~4~~ 90/004,946

Applicant(s)

AINSWORTH ET AL.

Examiner

Sharon Kennedy

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

3 (THREE)

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 26, 2001 (amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Response to Arguments Concerning Claims to be Examined

Patentee argues that claims 7-56 are not under reexamination, however, as stated in the Decision on Petition, paper no. 16 of the 90/004,946 reexamination application (hereinafter the RX-'946 application), the examiner's actions and any responses in a merged proceeding will apply to both the reissue application and the reexamination proceeding. Accordingly, all claims are under examination in each of the applications. For clarification, patentee is urged to review, in detail, MPEP 2285 IV, entitled "Conduct of Merged Reissue Application and Reexamination Proceeding." The pertinent portion is reproduced below:

In any merged reissue application and reexamination proceeding, each Office action issued by the examiner will take the form of a single action which jointly applies to both the reissue application and the reexamination proceeding. Each action will contain identifying data for both the reissue application and the reexamination proceeding, and each action will be physically entered into both files, which will be maintained as separate files.

In addition, application is reminded that the merged examination is being examined in accordance with 37 CFR 1.171-1.179, or according to reissue rules. See 37 CFR 1.565, or MPEP 2285, the pertinent portion being reproduced below.

The examiner, in examining the merged proceeding, will apply the reissue statute, rules, and case law to the merged proceeding. This is appropriate in view of the fact that the statutory provisions for reissue applications and reissue application examination include provisions equivalent to 35 U.S.C. 305 relating to the conduct of reexamination proceedings.

Patentee is reminded of the scope of examination in this application, which is set forth in MPEP 1445, reproduced below. There are no limits on the scope of examination.

1445 Reissue Application Examined in Same Manner as Original Application

As stated in 37 CFR 1.176, a reissue application, including all the claims therein, is subject to "be examined in the same manner as a non-reissue, non-provisional application." Accordingly, the claims in a reissue application are subject to any and all rejections which the examiner deems appropriate. It does not matter whether the claims are identical to those of the patent or changed from those in the patent. It also does not matter that a rejection was not made in the prosecution of the patent, or could have been made, or was in fact made and dropped during prosecution of the patent; the prior action in the prosecution of the patent does not prevent that rejection from being made in the

reissue application. Claims in a reissue application enjoy no "presumption of validity." *In re Doyle*, 482 F.2d 1385, 1392, 179 USPQ 227, 232-233 (CCPA 1973); *In re Sneed*, 710 F.2d 1544, 1550 n.4, 218 USPQ 385, 389 n.4 (Fed. Cir. 1983). Likewise, the fact that during prosecution of the patent the examiner considered, may have considered, or should have considered information such as, for example, a specific prior art document, does not have any bearing on, or prevent, its use as prior art during prosecution of the reissue application.

Patentee is also reminded that responses are filed in duplicate for entry in both files. The pertinent portion of MPEP 2285 is reproduced for patentee's convenience.

Any response by the applicant/patent owner in such a merged proceeding must consist of a single response, filed in duplicate for entry in both files (or provide multiple copies if there are multiple reexamination proceedings being merged with a reissue application), and service of copy must be made on any third party reexamination requester. A copy of all Office actions will be mailed to the third party reexamination requester but not to any other third party.

The claim format for both the reexamination file and the reissue file follow the rules in accordance with reissue practice. For patentee's convenience, the pertinent portion of MPEP 2285 is again reproduced below.

If a reissue application examination and a reexamination proceeding are merged, the merged examination will be conducted on the basis of the rules relating to the broader reissue application examination. Amendments should be submitted in accordance with the reissue practice under 37 CFR 1.121(* >i<) and 37 CFR 1.173; see MPEP § 1453.

Notice of Allowance Vacated--Reissue Application

Patentee is advised that the Notice of Allowance mailed April 6, 2000 in the Reissue application 09/143,503 is vacated. It is noted that the issue fee has already been paid. Patentee may request a refund or request that the fee be credited to a deposit account. However, patentee may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, patentee may request that the previously submitted issue fee be applied. If abandoned, patentee may request refund or credit to a specified Deposit Account.

Claim Rejections - 35 USC § 103

Claims 18, 19, 22, 31-36, 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al., US 5,316,706 in view of Beisel, WO 94/01160. Muni discloses a catheter made from crystallizable material such as PEEK (see column 4, lines 29-35) which is extruded to increase the stiffness of the catheter. The catheter has a stiff body and a soft pliable tip. Muni fails to disclose anything about tensile strength, elongation or tensile modulus, which is not uncommon in the catheter art. Beisel, WO 94/01160 recites the required data for a PEEK catheter on page 7 therein and exemplifies that the ranges recited in the claims are normal ranges for PEEK polymer catheters. Beisel does not explicitly state that this inner tube is extruded, but

Art Unit: 3762

discusses the concepts as generally known processes for producing catheters.

Accordingly, it would be obvious to one of ordinary skill in the art to make the Muni PEEK catheter in the claimed desirable ranges explicitly disclosed by Beisel for the purpose of making a catheter having a specific range of properties. Regarding claims 43-48; note that the Muni catheter is suitable for angioplasty. Regarding the claimed lengths, it does not appear that Muni discloses a length, however, lengths are obvious design choices dependent on patient need. Catheters are made for babies, basketball players, and everyone sized in between.

Claims 20, 21, 37-42, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni '706 in view of Beisel WO '160 as applied to claims 18, 54 above, and further in view of Bennett et al., US 5,221,728. The recited references fail to mention the elongation at break data, which is not uncommon in the catheter art. Bennett happens to mention the data and provides evidence that the claimed elongation is inherent or at least an obvious range.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al., '706 in view of Beisel, WO '160 as applied to claims 18, 22 above, and further in view of Cornelius et al., US 5,423,754. These claims point out the particular catheter structure desired. Cornelius exemplifies that the structure of inner and outer catheters, and the dilation balloon, with the various hard and soft areas are well known. It would be obvious to one of ordinary skill in the art to make the Cornelius catheter with

the common PEEK catheter polymer, dependent on patient need and the method of operating the catheter in the body.

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni '706 in view of Beisel, WO-'160 and Cornelius '754. Muni discloses a catheter made from crystallizable material such as PEEK (see column 4, lines 29-35) which is extruded to increase the stiffness of the catheter. The catheter has a stiff body and a soft pliable tip. Muni fails to disclose anything about tensile strength, elongation or tensile modulus, which is not uncommon in the catheter art. Beisel, WO 94/01160 recites the required data for a PEEK catheter on page 7 therein and exemplifies that the ranges recited in the claims are normal ranges for PEEK polymer catheters. Beisel does not explicitly state that this inner tube is extruded, but discusses the concepts as generally known processes for producing catheters. Accordingly, it would be obvious to one of ordinary skill in the art to make the Muni PEEK catheter in the claimed desirable ranges explicitly disclosed by Beisel for the purpose of making a catheter having a specific range of properties. The claims also call for a particular construction. Cornelius exemplifies that the structure of inner and outer catheters, and the dilation balloon, with the various hard and soft areas are well known. It would be obvious to one of ordinary skill in the art to make the Cornelius catheter with the common PEEK catheter polymer, dependent on patient need and the method of operating the catheter in the body.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muni '706 in view of Beisel WO '160 and Cornelius '754 as applied to claim 1 above, and further in view of Bennett '728. The recited references fail to mention the elongation at break data, which is not uncommon in the catheter art. Bennett happens to mention the data and provides evidence that the claimed elongation is inherent or at least an obvious range.

Response to Arguments Set Forth in the Reexamination Request

1. The phrase "proximal shaft portion formed at least in part of" is definite.

The requestor argues on page 8 that the claims are vague for reciting "a proximal shaft portion formed at least in part of" the material. The requestor argues that such language can include co-extruded layers, each having different physical properties, or even a braid. This is not found persuasive. The proper way of interpreting the claim scope is by examining the entirety of the patent, particularly all the claims, and in this case, the explanation is found in the Background of the Prior Art section of the specification. The claim means that part of **a length of** the shaft is formed of the polymer. This would be the "stiffened proximal shaft section". To further clarify, the claim means that maybe, e.g. 10 inches of the proximal shaft could be formed of the polymer. (It is noted that no dimensions are provided for only the stiffer section, but this would be a reasonable length dependent on the individual patient.) This interpretation is made clear when reviewing claim 5, wherein at least "one of the inner and the outer tubular members" are "formed of" the polymeric material. Accordingly, this claim is

interpreted according to a mechanical engineer's perspective--the "portion" applies to a length of the shaft. Certainly, following the requestor's reasoning, if a "portion" applied to a polymeric portion, the claim would be indefinite because the specification fails to provide guidance concerning how much polymer is necessary, and what it should be mixed with, to make the invention. There are no suggestions of mixing the polymer, and no examples are provided. This "mechanical engineering" interpretation is also correct since this application is being reviewed by the mechanical engineering branch of the patent office, and was examined by mechanical engineers, not chemists who would assume requestor's position.

2. Extruding thin-walled tubing is well known.

Requestor argues that Ainsworth did not discover that the process of extruding thin-walled tubing of certain engineering thermoplastic polymeric materials improves the physical properties of the material compared to the published physical properties. Requestor argues that this is well known. The examiner agrees. The extrusion principles, in general, are common and ordinary, as asserted. The examiner has also cited additional patents that show extruding tubes to form catheters is well known. However, this does not mean that the application of extrusion technology to a particular subject matter is automatically unpatentable for every situation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to patentee's disclosure. The patent to Engelson et al., US 5,312,356, discloses an

Art Unit: 3762

extruded catheter having a stiff proximal portion and a softer distal portion. Some data is provided in column 6, but it is not clear what this data represents. Engelson exemplifies that catheters, even if their flexibilities and stiffnesses are explicitly stated, rarely provide useful information that can be used to reject claims that base patentability on data points and ranges. The Engelson '356 patent references US Patents 4,680,156 and 4,499,041 (see column 11, line 17 of Engelson '356) which are also cited. The patent to Woinowski, US 4,277,432 is cited to show an early patent discussing extruding tubes to make catheters. The patent to Satchell et al., US 4,276,250 is an early patent discussing extruding tubes to form catheters having stiffer proximal ends and softer distal ends. As is typical for these patents, no data on stiffness is provided. Wijayarathna, US 4,464,176 is another catheter patent having a stiff proximal portion and a softer distal portion. As in the previous patents, the tensile strength, flexural strength, elongation at break data is not provided, however, this discusses the flexural modulus which is 300,000 psi, exemplifying that patentee's data is typical. Fontirroche et al., US 5,063,018 discloses a generic extrusion method.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571/272-6996.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Kennedy
Primary Examiner
Art Unit 3762